510(k) Summary

JUL 1 2002

Trade Name:	**BioFastin RC Threaded Suture Anchor**
Sponsor:	Mitek Worldwide 249 Vanderbilt Avenue Norwood, MA 02062 Registration #1221934
Contact:	Ruth Forstadt, Senior Regulatory Affairs Associate
Device Generic Name:	Fastener, Fixation, Biodegradable Soft Tissue
Classification:	According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.
Product Code:	87 MAI
Predicate Device(s):	FASTIN RC Suture Anchor Mitek CuffTack Sutureless Fixation Device PANALOK RC Absorbable Anchor
Product Description:	The BIOFASTIN RC Threaded Suture Anchor is an absorbable, threaded suture anchor. The BIOFASTIN RC anchor has 2 threads of an auger-type design with an overall nominal diameter of 5.0 mm and nominal length of 11.5 mm. The device has two suture holes (90 degrees apart) in the anchor head for fixation of #2 suture to bone (sutures provided pre-attached with affixed tapered needles). The sutures provided with the BIOFASTIN RC are either the ETHIBOND non-absorbable or PANACRYL absorbable sutures.
Indications for Use:	The BIOFASTIN RC Threaded Suture Anchor is indicated for shoulder rotator cuff repair.
Safety and Performance:	Results of performance testing have demonstrated that the modified device is substantially equivalent to the predicate devices.

Conclusion:
Based on 1) safety and performance data, and 2) similarities in design, operating principles, biocompatibility and sterilization method, the BIOFASTIN RC Threaded Suture Anchor has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

Ms. Ruth C. Forstadt
Senior Regulatory Affairs Associate
Mitek Worldwide
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K021883
Trade/Device Name: BIOFASTIN RC Threaded Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Codes: HWC, MAI, GAM, GAS
Dated: June 6, 2002
Received: June 7, 2002

Dear Ms. Forstadt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021883

Device Name: **BIOFASTIN RC Threaded Suture Anchor**

Indications for Use:

The BIOFASTIN RC Threaded Suture Anchor is indicated for shoulder rotator cuff repair.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

NRB for cmw

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021883

Prescription Use X OR Over-the -Counter Use ____
(Per 21 CFR 801.109)